ORAL ARGUMENT NOT YET SCHEDULED

No. 24-1188 (lead, consolidated with No. 24-1191, No. 24-1192)

In the United States Court of Appeals For the District of Columbia Circuit

American Water Works Association and Association of Metropolitan Water Agencies,
Petitioners,

v.

United States Environmental Protection Agency, and Michael S. Regan, in his official capacity as Administrator, United States Environmental Protection Agency,
Respondents.

ON PETITION FOR REVIEW FROM FINAL RULE OF THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,
89 FED. REG. 32,532 (APR. 26, 2024)

BRIEF OF THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

Matthew Z. Leopold
Javaneh Tarter
Hunton Andrews Kurth LLP
2200 Pennsylvania Ave. NW
Washington, DC 20037
(202) 955-1932

Andrew R. Varcoe
Stephanie A. Maloney
U.S. Chamber Litigation Center
1615 H Street, NW
Washington, DC 20062
(202) 463-5337

Elbert Lin
David M. Parker
Hunton Andrews Kurth LLP
951 East Byrd Street, East Tower
Richmond, VA 23219
dparker@huntonak.com
elin@huntonak.com
(804) 788-7202

Counsel for Amicus Curiae

CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

In accordance with D.C. Circuit Rule 28(a)(1), *amicus curiae* states as follows:

I. Parties, Intervenors, and *Amici Curiae*

Except for the following, all parties, intervenors, and *amici* appearing in this Court are listed in the Opening Brief of Petitioners American Water Works Association and Association of Metropolitan Water Agencies at page i; and the Brief for Petitioners National Association of Manufacturers, American Chemistry Council, and The Chemours Company FC, LLC at page iii.

Amicus curiae in support of Petitioners is the Chamber of Commerce of the United States of America. The State of Connecticut has indicated the intent to participate as *amicus curiae* in support of Respondents.

II. Rulings Under Review

References to the rulings at issue appear in the Opening Brief of Petitioners American Water Works Association and Association of Metropolitan Water Agencies at page ii.

III. Related Cases

This case has been consolidated with the following petitions for review of the same EPA final rule: *National Association of Manufacturers, et al. v. EPA, et al.* (No. 24-1191), and *The Chemours Company FC, LLC v. EPA, et al.* (No. 24-1192). *Amicus curiae* is aware of no other related cases within the meaning of D.C. Circuit Rule 28(a)(1)(C).

CORPORATE DISCLOSURE STATEMENT

The Chamber of Commerce of the United States of America ("Chamber") is a non-profit, tax-exempt organization incorporated in the District of Columbia. The Chamber has no parent corporation, and no publicly held company has 10% or greater ownership in the Chamber.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Other Authorities

GLOSSARY OF TERMS

ATSDR	Agency for Toxic Substances and Disease Registry
Chamber	Chamber of Commerce of the United States of America
EPA	Environmental Protection Agency
HFPO-DA	Hexafluoropropylene oxide dimer acid
HISA	Highly Influential Scientific Assessments
ISI	Influential Scientific Information
PFAS	Per-and-polyfluoroalkyl substances
PFBS	Perfluorobutane sulfonic acid
PFHxS	Perfluorohexane sulfonic acid
PFNA	Perfluorononanoic acid
PFOA	Perfluorooctanoic acid
PFOS	Perfluorooctane sulfonic acid
ppt	Parts per trillion
SDWA PFAS Rule or Final Rule	PFAS National Primary Drinking Water Regulation
SDWA	Safe Drinking Water Act

STATUTES AND REGULATIONS

All applicable statutes and regulations are included in the Statutory and Regulatory Addendum of Petitioners American Water Works Association and Association of Metropolitan Water Agencies.

INTEREST OF *AMICUS CURIAE*[1]

The Chamber of Commerce of the United States of America ("Chamber") is the world's largest business federation. It represents approximately 300,000 direct members and indirectly represents the interests of more than three million companies and professional organizations of every size, in every industry sector, and from every region of the country. An important function of the Chamber is to represent the interests of its members in matters before Congress, the Executive Branch, and the courts. To that end, the Chamber regularly files *amicus curiae* briefs in cases, like this one, that raise issues of concern to the nation's business community.

[1] No counsel for any party authored this brief in whole or in part, and no entity or person, aside from amicus, its members, or its counsel, made any monetary contribution intended to fund the preparation or submission of this brief.

The Chamber is well-situated to aid the Court's review of EPA's regulation of per-and-polyfluoroalkyl substances ("PFAS") under the Safe Drinking Water Act ("SDWA"). PFAS National Primary Drinking Water Regulation, 89 Fed. Reg. 32,532 ("SDWA PFAS Rule" or "Final Rule"). The Chamber represents members that span key U.S. supply chains utilizing a wide range of substances within the class of PFAS, whose products and technologies are essential to America's economic growth, water infrastructure, and national security. Many of these companies operate public water systems, including "Non-Transient Non-Community Water Systems" that are regulated by the SDWA PFAS Rule. The Chamber's members face an unprecedented burden of significant and unjustified costs imposed directly and indirectly by this rule. Further, EPA's determinations to support the rule are not based on the best available science, as required for setting a national primary drinking water regulation under SDWA. A Chamber-led coalition filed extensive comments on the rule when it was proposed, expressing serious concerns about these and other legal and policy issues in considerable detail.

Comments of the U.S. Chamber of Commerce and Its Coalition, EPA-HQ-OW-2022-0114-1759 (May 30, 2023).[2]

Pursuant to Circuit Rule 29(d), the Chamber certifies that it is aware of no other *amicus curiae* that intends to file a brief in support of Petitioners.

INTRODUCTION AND SUMMARY OF ARGUMENT

This case presents a challenge to an EPA final rule that governs six specific PFAS substances in drinking water under the Safe Drinking Water Act. The term "PFAS" encompasses an entire class of chemical substances. Petitioners' Br. at 3–4. The six specific PFAS that EPA regulates under the Final Rule are known by the acronyms PFOA, PFOS, PFHxS, PFNA, HFPO-DA, and PFBS.[3] In light of their use in a variety of contexts, EPA has said that PFAS substances are present in public water systems nationwide.

---

[2] https://www.regulations.gov/comment/EPA-HQ-OW-2022-0114-1713.

[3] These are perfluorooctanoic acid, perfluorooctane sulfonic acid, perfluorohexane sulfonic acid, perfluorononanoic acid, hexafluoropropylene oxide dimer acid, and perfluorobutane sulfonic acid, respectively.

The Chamber supports the goal of national primary drinking water regulations under SDWA to reduce contaminants in drinking water. National standards would help avoid a patchwork of state actions, promoting certainty and consistency for businesses and other impacted stakeholders. More broadly, the Chamber supports the safe management of PFAS and protecting human health and the environment. However, the Final Rule is problematic in several respects, including that it would impose enormous costs on the economy without obtaining the benefits that SDWA is designed to deliver. This imbalance in the Final Rule does not comply with the careful approach that SDWA requires.

The Final Rule is expected to directly affect more than 66,000 nation-wide public water systems, serving 90% of Americans. Most of these water systems—62,000—are small public water systems.[4] 89 Fed. Reg. at 32,722. These systems will be required to comply with Maximum Contaminant Levels—which dictate the highest permitted concentrations of a substance—for five of the six PFAS on an individual basis.[5] The systems will also be required to comply with a Hazard

[4] Small public water systems serve between 25 and 10,000 people.

[5] PFOA, PFOS, PFHxS, PFNA, and HFPO-DA.

Index—something EPA has never used in the SDWA context—that measures the combined harm from certain mixtures of the covered PFAS.[6]

The Final Rule sets Maximum Contaminant Levels at 4 parts per trillion ("ppt") for two PFAS (PFOA and PFOS) and 10 ppt for the other three PFAS (PFNA, PFHxS, and HFPO-DA). The amount of PFAS at these levels is minuscule—one part per trillion is equivalent to *one drop of water* in 20 Olympic-sized swimming pools.[7]

These Maximum Contaminant Levels will impose substantial costs and burdens on public water systems merely to *monitor* these PFAS. While EPA finds it to be *technically* achievable to treat drinking water to these infinitesimal levels of PFAS, it gives short shrift to the *affordability* of this mandate. EPA relies on non-recurring federal funding from the Bipartisan Infrastructure Law to kickstart this process,

---

[6] The Hazard Index applies to mixtures comprising two or more of PFHxS, PFNA, HFPO-DA, and PFBS.

[7] *See* Missouri Department of Natural Resources, *Understanding Data*, https://dnr.mo.gov/monitoring/understanding-data#:~:text=One% (last visited Oct. 15, 2024).

but that temporary funding simply isn't sufficient, even if actually available now.

The Final Rule should be vacated because it is arbitrary and capricious, and exceeds statutory authority, including by violating the Safe Drinking Water Act's requirement that EPA use best available science in its decision making. This brief focuses on two of the fundamental problems with the Final Rule.[8]

First, EPA failed to accurately assess the likely costs and consequences of its rule. SDWA permits only cost-effective rules, which requires an appropriate assessment of the costs of the rule in order to weigh them against the rule's benefits. And the Administrative Procedure Act requires agencies to consider the likely consequences of their decisions before making those decisions. Here, EPA ignored billions of dollars that communities, homeowners, and other ratepayers will likely pay under the Final Rule to modify their facilities to monitor and to remove the requisite tiny levels of PFAS. EPA exacerbated this error

[8] The Chamber agrees with Petitioners that the Final Rule is invalid on several other grounds, including that EPA unlawfully short-circuited the express procedure mandated by SDWA for proposing to regulate substances.

by relying on temporary funds from the Bipartisan Infrastructure Law that will soon disappear.

Second, EPA failed to comply with SDWA's clear mandate to use the best available science when EPA decided to regulate PFAS in the first place. Much of the science EPA relies on to justify its rule is incomplete and inconclusive. For one thing, the "Hazard Index" EPA finalized for certain mixtures of two or more PFAS is unprecedented in *any* nationwide rulemaking. Moreover, the Hazard Index is not appropriate for SDWA because it is a screening-level tool—meaning that it is designed for quick sorting followed by closer scrutiny, and thus deliberately over-predicts risk. In addition, for four of the six PFAS at issue, EPA violated SDWA's requirement that EPA consult its own Science Advisory Board, an independent review board authorized by Congress specifically to review scientific information being used by EPA as the basis for its regulations.

ARGUMENT

I. EPA failed to properly assess the costs and benefits of the SDWA PFAS Rule.

The Safe Drinking Water Act requires EPA to promulgate cost-effective rules, meaning the costs of the rule must be justified by the

benefits. As a threshold matter, that requires EPA to accurately assess the costs. But EPA failed to do that here. And even a passing review reveals significant defects in EPA's analysis of benefits.

A. SDWA permits only cost-effective rules.

SDWA does not give EPA a free hand to impose regulations notwithstanding the cost of those rules. Rather, it requires a detailed assessment of costs, which must be balanced against the expected benefits. Indeed, that assessment is required at multiple steps in the rulemaking process, serving the overarching purpose of ensuring that EPA's drinking-water regulations will be cost-effective.

First, EPA must accurately assess costs at the very beginning of its rulemaking. When first proposing a drinking-water regulation such as the Final Rule (that is, one that contains a Maximum Contaminant Level), EPA must publish, seek public comment on, and "use" an analysis of the "quantifiable and nonquantifiable costs" that are "likely to occur solely as a result of compliance with the [Maximum Contaminant Level]." 42 U.S.C. § 300g-1(b)(3)(C)(i)(III). These include the costs of monitoring and treatment. *Id.* EPA must also publicly determine whether the

benefits of the Maximum Contaminant Level justify the costs. *Id.* § 300g-1(b)(4)(C).

Next, if EPA then determines, after considering public comment, that its proposed rule is *not* cost-effective—because the benefits of the proposed Maximum Contaminant Level do *not* justify the costs of compliance—EPA may propose a new Maximum Contaminant Level. *Id.* § 300g-1(b)(6)(A). Then, after notice and comment on the revised level, and after EPA properly concludes that the revised level would be cost-effective, EPA can promulgate a rule. *Id.*

Finally, SDWA requires that the Maximum Contaminant Level "shall not be more stringent than is feasible." *Id.* § 300g-1(b)(5)(B)(ii). SDWA defines "feasible" to require "taking cost into consideration." *Id.*

B. EPA failed to adequately assess the costs of the SDWA PFAS Rule.

According to EPA, the quantifiable annual costs and quantifiable annual benefits of the Final Rule are a wash, each being approximately $1.55 billion. 89 Fed. Reg. at 32,533. But that assessment excludes billions of dollars that water-treatment systems, homeowners, and other ratepayers will be forced to pay as a result of this rule. Accordingly, EPA's assessment is arbitrary and capricious, requiring vacatur of the rule. 42

U.S.C. § 300g-1(b)(6)(D). Multiple studies confirm that compliance costs for PFOA and PFOS will be substantially higher than EPA predicts.

First is a study submitted by Petitioners American Water Works Association and Association of Metropolitan Water Agencies ("Black & Veatch Study"). Focusing just on *two* of the covered PFAS (PFOA and PFOS), the study found that when the Maximum Contaminant Levels are set at 4 ppt, the annual cost of compliance will be almost *three times higher* than EPA's estimate of $1.5 billion annually for all *six* PFAS. *See* AWWA, *Costs of Removing PFAS from Drinking Water*;[9] *see also* Black & Veatch Study at Appendix A, Table A-5.

The Black & Veatch Study estimates annual compliance costs for PFOA and PFOS alone at $2.5 billion to $3.2 billion (depending on the discount rate). These costs will be borne by individuals and other ratepayers, such as businesses, that are customers of the drinking water utility, and vary considerably based on the size of the water utility. For example, the costs to households could be $100 or more per year for utilities serving more than one million people. Black & Veatch Study at

[9] https://www.awwa.org/wp-content/uploads/PFAS-Costs-Fact-Sheet.pdf (last visited Oct. 15, 2024).

33. But that cost climbs to $3,570 a year for utilities serving fewer than one hundred people, given the need to install and operate new treatment technologies. *Id.* And those are just the costs attributable to PFOA and PFOS. The Black & Veatch Study does not address the other three PFAS substances that now have individual Maximum Contaminant Levels or the four PFAS that, as a mixture, now have a Hazard Index Maximum Contaminant Level.

The Black & Veatch Study relied on far more current cost data than EPA and considered the effect of thousands of water systems trying all at once to put in place the same treatment technologies. *See* EPA, Response to Public Comments on Per-and-Polyfluoroalkyl Substances (PFAS) National Primary Drinking Water Regulation (April 2024) ("Response to Comments"), at 3,815. The simultaneous, nationwide rush will increase demand for laboratories, engineering consultants, planners, contractors skilled treatment operators, which in turn increases price. *Id.* EPA ignored these factors.[10]

---

[10] EPA asserted that the Black & Veatch study over-estimates costs to water-treatment systems by assuming that all are *not* in compliance with state PFAS regulations when some are already in compliance because of state regulation. Response to Comments at 3,708. However, — *footnote cont'd* —

In contrast, EPA miscalculated drastically lower costs through stale data and flawed reasoning. EPA based its assumptions about water use on data from the 1990s and published in 2000. *See id*. at 3,709. EPA also relied on outdated construction-cost data that does not reflect recent price increases arising from the COVID-19 pandemic, supply-chain disruption, and higher interest rates.[11]

Second, a study conducted by the Chamber further confirms that compliance costs relating to just PFOA and PFOS will be significantly higher than EPA predicts.

This study initially estimated *total* water-treatment costs of $10 billion to $12 billion (in 2020 dollars), assuming a Maximum Contamination Level of 10 ppt or less (with approximately $1.8 billion in

---

the Black & Veatch study estimates separately, and removes from the national cost estimate, the PFAS treatment costs associated with compliance with state Maximum Contaminant Levels. Black & Veatch study at 29.

[11] For example, the Black & Veatch Study incorporated real-world contingency factors in its capital-cost assumptions, such as 4% for contractor markups and 30% for non-construction costs. These multipliers are standard, based on the recommendations of the American Association of Cost Engineering Recommended Practices. Black & Veatch Study at 23. EPA's cost estimate incorporated only a 5% to 10% contingency based on total project cost plus a 10% miscellaneous allowance. 89 Fed. Reg. at 32,640.

annual costs). U.S. Chamber of Commerce, *Potential Costs of Meeting Safe Drinking Water Act (SDWA) Standards for PFOA and PFOS* at 3 (November 7, 2022).[12] Costs increase greatly if the Maximum Contaminant Level is set below 10 ppt. *Id.* at 3. When levels for PFOA and PFOS are set at 10 ppt, total estimated costs are approximately $11.7 billion. But when the levels are set lower at a "non-detect scenario" (the level below detection), costs nearly quadruple, to $43.2 billion. *Id.* at 7.

The Chamber then updated its study, calculating costs at a Maximum Containment Level of 4 ppt (in 2022 dollars). *Id.* at 12. The Chamber's report estimated that costs skyrocket to approximately $32.5 billion. *Id.* For the non-detect scenario, the estimated costs jump to approximately $59.4 billion (again, in 2022 dollars). *Id.*

EPA, of course, has now promulgated a Maximum Contamination Level of *4* ppt for PFOA and PFOS. And, again, these are just the estimated costs of the impact of Maximum Contaminant Levels for PFOA and PFOS—not all the PFAS substances at issue in the Final Rule.

---

[12] https://www.globalenergyinstitute.org/potential-costs-meeting-safe-drinking-water-act-sdwa-standards-pfoa-and-pfos.

C. EPA cannot justify these costs with non-recurring federal funding.

EPA attempts to justify the costs to comply with the Final Rule by relying on the Bipartisan Infrastructure Law, which, EPA says, will defray the costs of compliance. EPA's reasoning ignores a key aspect of the problem: these funds are simply inadequate.

To begin, current access to these funds is speculative. By EPA's calculation, the Bipartisan Infrastructure Law invests approximately $20 billion in safe drinking water over a five-year period, using funds and grants to address emerging contaminants. 89 Fed. Reg. at 32,534, 32,538. But those funds are designed to address far more than just PFAS, including lead-pipe replacement.[13] Accordingly, funding to address PFAS in every impacted public water system is far from guaranteed. In addition, that funding would take time—water systems would have to

[13] On October 8, 2024, EPA just finalized a rule requiring drinking water systems to identify and replace lead pipes within 10 years, which EPA intends to fund through the Bipartisan Infrastructure Law. *See* EPA, *Biden-Harris Administration Requires Replacement of Lead Pipes Within 10 Years, Announces Over $168M in Funding to EPA Region 8 States* (Oct. 8, 2024), https://www.epa.gov/newsreleases/biden-harris-administration-requires-replacement-lead-pipes-within-10-years-announces.

apply for funding while, in the meantime, incurring compliance costs until receiving funds, if any.

Further, this funding may be temporary. To the extent water systems' costs outlast the short-term funding available through the Bipartisan Infrastructure Law, the systems will face compliance costs in an unfunded mandate, costs that will be paid by communities and other ratepayers.

D. EPA's evaluation of the benefits of the SDWA PFAS Rule was deficient.

EPA not only underestimated the costs of the Final Rule, it overestimated the benefits as well. SDWA required EPA to use best available science and provide a factual basis when EPA evaluated the benefits from the Final Rule. 42 U.S.C. § 300g-1(b)(3)(C). In concluding that the benefits of the Final Rule are "nearly at parity" with the rule's costs, 89 Fed. Reg. at 32,533, EPA did not comply with SDWA's requirements.

EPA's assessment of the benefits of the Final Rule is based on its estimate that that there will be "29,858 fewer illnesses and 9,614 fewer deaths in the decades following actions to reduce PFAS levels in drinking

water." *Id.* EPA has not provided a sound scientific basis for this statement.

In particular, EPA touts supposed reductions in cardiovascular disease. 89 Fed. Reg. at 32,683. But EPA concedes that it relied on studies considered to be low quality, 89 Fed. Reg. at 32,636, and notes that the data on which it relies is "not conclusive." PFAS National Primary Drinking Water Regulation Rulemaking, 88 Fed. Reg. 18,638, 18,704 (March 29, 2023) (noting that the "[e]vidence of the relationship between the PFAS compound and the health outcome is not conclusive"); Response to Comments at 3,945; 89 Fed. Reg. at 32,683 (literature "does not provide direct support for an effect of PFOA and PFOS on the risk of [cardiovascular disease]"); Public Comment Draft, Toxicity Assessment and Proposed Maximum Contaminant Level Goal for [PFOS] in Drinking Water at 214 (March 2024) ("While there is some evidence that PFOS exposure *might* also have the *potential* to affect blood pressure and other cardiovascular responses in humans given relevant exposure circumstances, the human evidence underlying this possibility is uncertain and without support from animal or mechanistic studies.") (emphasis added).

II. EPA failed to use the best available science when it decided to regulate PFAS.

In carrying out SDWA, to the degree EPA bases an action on science, EPA is required to use "the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices" when deciding whether to regulate a substance. 42 U.S.C. § 300g-1(b)(3)(A)(i). EPA is also required to consult with its Science Advisory Board before proposing a drinking-water regulation. 42 U.S.C. § 300g-1(e). EPA failed in both respects.

A. The Hazard Index approach used to establish Maximum Contaminant Levels and Maximum Contaminant Level Goals for mixtures of PFAS is not based on the best available science.

In addition to setting Maximum Contaminant Levels for five PFAS substances on an individual basis, EPA used for the first-time in the SDWA context a Hazard Index approach for *mixtures* of two or more of the following PFAS: PFBS, PFHxS, PFNA, and HFPO-DA. A Hazard Index measures the combined harm from a mixture of different chemicals. It is a sum of "hazard quotients" from each PFAS substance. The hazard quotient is the ratio of exposure of the individual PFAS to the level where adverse effects are not anticipated to occur—so a ratio of

less than 1 means no adverse health effects are expected to occur. In the Final Rule, EPA mixed and matched different health endpoints and combined them into a single Hazard Index. It examined *thyroid* harm from two PFAS (PFHxS and PFBS), *body-weight changes* for another PFAS (PFNA), and *liver lesions* for still another PFAS (HFPO-DA). It then blended all this data together to create a single Hazard Index.

The hazard-index approach is not best available science. This hazard index approach is a screening-level approach that is deliberately designed to overpredict any actual risks. If risk is identified, more refined evaluation is necessary to see if those risks are actually expected to occur. *See* EPA, *Exposure Assessment Tools by Tiers and Types- Screening Level and Refined* (May 6, 2024)."[14] It is not meant as a be-all-end-all for regulatory action.

That is what EPA's own Science Advisory Board told the Agency. The Science Advisory Board is tasked with reviewing the quality and relevance of scientific information EPA presents as the basis for its

[14] https://www.epa.gov/expobox/exposure-assessment-tools-tiers-and-types-screening-level-and-refined.

regulations, and the board provides recommendations to EPA.[15] As the Science Advisory Board told EPA, a Hazard Index approach that relies on different effects is appropriate only as a screening tool. EPA, *Transmittal of the Science Advisory Board Report titled, "Review of EPA's Analyses to Support EPA's National Primary Drinking Water Rulemaking for PFAS"* 92 (Aug. 22, 2022).[16] Specifically, the Science Advisory Board stated that a "Hazard Index (HI) approach . . . is appropriate for *initial* screening of whether exposure to a mixture of PFAS poses a *potential* risk." *Id.* (emphasis added). That risk should then be "*further* evaluated." *Id.* (emphasis added). The Science Advisory Board instead gave a favorable review for developing *different* mixture-assessment approaches.[17] But EPA rejected those approaches and went forward with the less refined Hazard Index approach to establish a

---

[15] EPA, *About the Science Advisory Board*, https://sab.epa.gov/ords/sab/r/sab_apex/sab/aboutthesab?session=3335706034637 (last visited Oct. 15, 2024).

[16] https://sab.epa.gov/ords/sab/f?p=114:0:7620061737328:APPLICATION_PROCESS=REPORT_DOC:::REPORT_ID:1105.

[17] *See* EPA, *Public Review Draft* at 4 (Mar. 2023), https://www.epa.gov/system/files/documents/2023-03/PFAS%20Mix%20Framework%20Public%20Review%20Draft%2009%20March%202023.pdf.

Maximum Contaminant Level for certain mixtures. That was not consistent with the Science Advisory Board's advice and does not reflect the best available science.

Indeed, using a Hazard Index approach to set a Maximum Contaminant Level is not permitted by the statute. The term "Maximum Contaminant Level" under SDWA means "the maximum permissible level of a contaminant in water which is delivered to any user of a public water system." 42 U.S.C. § 300f(3). SDWA contemplates setting Maximum Contaminant Levels for *each contaminant* individually and with a specific level, so that regulated entities can understand the levels that must be achieved for compliance. 42 U.S.C. § 300g-1(b)(1)(E).

SDWA does not allow EPA to set Maximum Contaminant Levels for a mixture, let alone by using a complex equation. The term "mixture" appears only twice in the statute, and it is related to drinking water studies of complex mixtures. 42 U.S.C. § 300j-18(b)(3). The statutory text reflects that Congress never intended for EPA to use Maximum Contaminant Levels to regulate mixtures of contaminants under SDWA rather than individual contaminants.

The Hazard Index approach is inconsistent with SDWA because it sets a limitation on a group of chemicals rather than the individual chemicals, and it does not set a "level" as contemplated by the statute. This is not a measurement in parts per million or any other set level that public water systems can reliably measure. The Hazard Index is a highly variable equation that public water systems have to calculate, and can change over time as inputs change as the health-based water concentration may change.

B. EPA used human-health data that did not reflect best available science.

1. EPA violated SDWA by failing to seek review from its Science Advisory Board for four of the six PFAS substances it is regulating.

In violation of SDWA, EPA failed to seek peer review from the Science Advisory Board for most of the PFAS substances regulated under the Final Rule.

SDWA expressly requires EPA to seek review from the Science Advisory Board for all PFAS substances EPA regulates under the Final Rule. The statute provides that EPA "*shall* request comments from the Science Advisory Board . . . prior to proposal of a maximum contaminant level goal and national primary drinking water regulation." 42 U.S.C.

§ 300g-1(e). EPA did not do that for PFHxS, PFNA, or HFPO-DA or for the Hazard Index for the specific mixture of PFAS regulated by this rule.

The Science Advisory Board process is far more robust than processes run by external contractors. For instance, the Science Advisory Board engages in deliberations and strives to reach consensus in all their reports because their final product is meant to be a consensus advisory report. EPA, *Serving on the EPA Science Advisory Board* (Mar. 2012).[18] The Science Advisory Board also must abide by ethics requirements (including financial disclosure requirements).[19] Further, the Science Advisory Board is a Federal Advisory Committee, so it must comply with the rigorous oversight, public involvement, and transparency requirements of the Federal Advisory Committee Act. 5 U.S.C. § 10.

This Court has recognized the importance of Science Advisory Board review when establishing drinking water levels under SDWA. In

---

[18] https://sab.epa.gov/ords/sab/r/sab_apex/files/static/v403/Serving%20on%20the%20EPA%20Science%20Advisory%20Board%20SABSO-12-001.pdf.

[19] EPA, *Ethics Requirements for Advisors*, https://sab.epa.gov/ords/sab/f?p=114:5:8938056644022 (last visited Oct. 15, 2024).

Chlorine Chemistry Council v. EPA, chlorine and chlorine-product manufacturers challenged EPA's Maximum Contaminant Level Goals for chloroform because EPA set these at zero based an internal policy for carcinogens. *Chlorine Chemistry Council v. EPA*, 206 F.3d 1286, 1287 (D.C. Cir. 2000). During the rulemaking process, the Science Advisory Board proved EPA wrong, finding that there was no carcinogenic effect at low thresholds. *Id.* at 1288. In the resulting litigation, EPA conceded in response to the Science Advisory Board's advice that EPA could no longer continue to defend its assessment. *Id. Chlorine Chemistry Council* demonstrates that the Science Advisory Board review can result in conclusions contrary to EPA's policies and, therefore, significantly alter the outcome of a proposed drinking-water standard.

2. EPA inappropriately relied on other external assessments that did not undergo robust peer review.

For two PFAS compounds, PFHxS and PFNA, EPA relied on a simple "letter review" peer-review process from the Agency for Toxic Substances and Disease Registry ("ATSDR"), a federal public health agency of the U.S. Department of Health and Human Services, to evaluate health assessments. In this "letter review" process, experts

individually review a proposal. They do not convene on a panel, they do not engage directly with public commenters, and their review is not governed by the Federal Advisory Committee Act, which helps ensure committee membership is fairly balanced. This is not the robust peer review process from the Science Advisory Board that SDWA requires.

Indeed, EPA's own guidelines contemplate more than the "letter review" it received for these two compounds. EPA's Peer Review Handbook describes best practices for the peer review of Influential Scientific Information ("ISI") or a subset of ISIs called Highly Influential Scientific Assessments ("HISAs"). EPA, Peer Review Handbook 40 (4th ed. 2015).[20] ISI is scientific information that EPA "reasonably can determine will have or does have a clear and substantial impact on important public policies or private-sector decisions." *Id.* at 42. A HISA is a scientific assessment that could have a potential impact of more than $500 million in a year or is "novel, controversial, precedent-setting or has significant interagency interest." *Id.* ISIs and HISAs receive extensive peer review. For HISAs, in particular, an external peer review panel is

[20] https://www.epa.gov/scientific-leadership/peer-review.

preferred. *Id*. at 55–57. A panel review is more robust and deliberative, allows for public input directly to panel members, and is governed by the Federal Advisory Committee Act. *See id*. at 75.

Regulation of PFAS in a nationwide rule that will cost $1.5 billion per year (according to EPA estimates) easily fits within the definitions of both Highly Influential Scientific Assessments and Influential Scientific Information. The costs and impact are enormous. Using a letter review, one of the least onerous forms of review, does not satisfy EPA's own Peer Review Handbook.

Even the Agency for Toxic Substances and Disease Registry would disagree with EPA's use of ATSDR's assessments. ATSDR describes the values they develop as "[i]ntended to serve as screening levels" that "are used by ATSDR health assessors and other responders to identify contaminants and potential health effects that may be of concern at hazardous waste sites." *See* ATSDR, Minimal Risk Levels (MRLs)—For Professionals (Feb. 8, 2024).[21] ATSDR states that its results are "*not*

[21] https://www.atsdr.cdc.gov/mrls/index.html.

intended to define cleanup or action levels" for anyone, including EPA. *Id.* (emphasis added).

CONCLUSION

The Court should vacate the Final Rule and remand to EPA.

Respectfully submitted,

/s/ Elbert Lin

Andrew R. Varcoe
Stephanie A. Maloney
U.S. Chamber Litigation Center
1615 H Street, NW
Washington, DC 20062
avarcoe@USchamber.com
(202) 463-5337

Elbert Lin
David Parker
Hunton Andrews Kurth LLP
951 East Byrd Street, East Tower
Richmond, VA 23219
elin@huntonak.com
dparker@huntonak.com
(804) 788-8200

Matthew Z. Leopold
Javaneh Tarter
Hunton Andrews Kurth LLP
2200 Pennsylvania Ave. NW
Washington, DC 20037
mleopold@huntonak.com
jtarter@huntonak.com
(202) 419-2057

Counsel for Amicus Curiae

October 15, 2024

CERTIFICATE OF COMPLIANCE

This brief contains 5,769 words excluding the parts of the brief that Federal Rule of Appellate Procedure 32(f) and D.C. Circuit Rule 32(e)(1) exempt. The brief thus complies with Federal Rules of Appellate Procedure 32(g) and 29(a)(5), as well as D.C. Circuit Rule 32(e)(3), because the word count does not exceed the 6,500 words permitted under those rules.

The brief also complies with Federal Rule of Appellate Procedure 32(a)(5)'s typeface requirements and Federal Rule of Appellate Procedure 32(a)(6)'s type style requirements (as well as Federal Rule of Appellate Procedure 27(d)(1)(E)) because the brief has been prepared in a proportionally spaced type-face using Microsoft Word in Century Schoolbook 14-point font.

CERTIFICATE OF SERVICE

I hereby certify that, on October 15, 2024, I electronically filed the foregoing brief with the Clerk of the Court for the U.S. Court of Appeals for the District of Columbia Circuit via the CM/ECF system. Participants

in the case who are registered CM/ECF users will be served by that system.

/s/ Elbert Lin
Counsel for *amicus curiae*